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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,948

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EXAMINER

ARCHIE, NINA

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

09/08/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,948	<b>Applicant(s)</b> SATO ET AL.	
	<b>Examiner</b> Nina A. Archie	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This Office is responsive to Applicant's amendment and response filed 5-2-08. Claim 5 has been amended. Claims 6-9 have been cancelled.

### **Objections/Rejections Withdrawn**

2.
  - a) Objection to claims 5-9 is withdrawn in light of applicant's amendment thereto and cancellation of claims (6-9).
  - b) Rejection of claim 6 under 35 U.S.C. 112, first paragraph is withdrawn in light of cancellation of the claim.
  - c) Rejection of claims 1-9 under 35 U.S.C. 103(a), is withdrawn in light of applicant's amendment thereto.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 102 and 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimkets et al WO/2001/048245.

Claims 1-2 and 5 are drawn to a polynucleotide comprising a CpG motif wherein guanine is methylated.

Shimkets et al teach to a polynucleotide (antisense nucleic acid molecule see SEQ ID NO:12) (see pg. 60) comprising a CpG motif wherein guanine is methylated (1-methylguanine) (see claims, pgs. 31-32), wherein the length is 8 to 100 nucleotides (see claims and pgs. 31-32).

Shimkets et al teach antisense nucleic acid molecules can be modified to target selected cells and then administered systemically. Therefore Shimkets et al teach a pharmaceutical composition which comprises the polynucleotide as an active ingredient and at least one pharmaceutically acceptable excipient.

4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al 1996 Nucleic Acids Research Vol. 24 No. 7 pgs. 1272-1278.

Claims 1-2 are drawn to a polynucleotide comprising a CpG motif wherein guanine is methylated.

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Sugiyama et al teach to a polynucleotide (see Table 3) comprising a CpG motif wherein guanine is methylated, wherein the length is 8 to 100 nucleotides (see pgs. 1272-1278 especially 1272 and Table 3 ).

5. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimkets et al WO 2001/42845A2 in view of Krieg et al WO/1998/018810 Date May 7, 1998.

Claims 1-5 are drawn to a polynucleotide a polynucleotide comprising a CpG motif wherein guanine is methylated.

Shimkets et al is relied upon as set forth supra. However Shimkets et al does not teach a nucleotide of any one of SEQ ID NOs: 1-4.

Krieg et al teach SEQ ID NO: 1 (see STIC RESULTS). Krieg et al teach methylated oligonucleotides (polynucleotide) comprising a CpG motif, wherein the length is 8 to 100 nucleotides.

Krieg et al further teach a pharmaceutical composition (see Krieg et al in its entirety).

It would have been prima facie obvious at the time the invention was made to produce a polynucleotide as taught by Krieg et al and to modify a polynucleotide comprising a CpG motif wherein guanine is methylated as taught by Shimkets et al because Shimkets et al teach an antisense nucleic acid of the invention can be constructed using chemical synthesis using procedures known in the art. For example, an antisense nucleic acid (e. g., an antisense oligonucleotide) can be chemically synthesized using naturally occurring nucleotides or variously modified nucleotides designed to increase the biological stability of the molecules or to increase the physical stability of the duplex formed between the antisense and sense nucleic acids, e. g., phosphorothioate derivatives and acridine substituted nucleotides can be used.

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6. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiyama et al 1996 Nucleic Acids Research Vol. 24 No. 7 pgs. 1272-1278 in view of Krieg et al WO/1998/018810 Date May 7, 1998.

Claims 1-4 are drawn to a polynucleotide a polynucleotide comprising a CpG motif wherein guanine is methylated.

Sugiyama et al is relied upon as set forth supra. However Sugiyama et al does not teach a nucleotide of any one of SEQ ID NOs: 1-4.

Krieg et al teach SEQ ID NO: 1 (see STIC RESULTS). Krieg et al teach methylated oligonucleotides (polynucleotide) comprising a CpG motif, wherein the length is 8 to 100 nucleotides.

It would have been prima facie obvious at the time the invention was made to produce a polynucleotide comprising a polynucleotide as taught by Krieg et al and to modify a polynucleotide comprising a CpG motif wherein guanine is methylated as taught by Sugiyama et al because the presence of m8G in d(CGC[m8G]CG)<sub>2</sub> stabilizes the Z conformation and that the Z conformation was further stabilized by increasing the number of m8Gs incorporated and destabilized by incorporating syn-A or syn-T, found respectively in the (A,T)-containing alternating and non-alternating pyrimidine–purine sequences. Sugiyama et al results suggest that the chemically less reactive m8G base is a useful agent for studying molecular interactions of Z-DNA or other DNA structures that incorporate syn-G conformation. Sugiyama et al report herein that the introduction of a methyl group at the guanine C8 position produces a stable m8-modified guanine base and markedly stabilizes the Z conformation if short oligonucleotides of a variety of sequences under physiological salt conditions.

### ***Status of the Claims***

7. No claims are allowed.  
Claims 1-5 are rejected.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisors, Shanon Foley can be reached on 571-272-0898 and Robert Mondesi at 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1645

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